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A Long-Term Treatment Outcome of Abdominal Sacrocolpopexy

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Purpose: The aim of this study was to evaluate the long-term treatment outcome and major complication rates of abdominal sacrocolpopexy (ASC). **Materials and Methods:** This retrospective study included 57 Korean women who underwent ASC with mesh for symptomatic uterine or vault prolapse and attended follow-up visits for at least 5 years. Forty-seven women with urodynamic stress incontinence concomitantly received a modified Burch colposuspension. The long-term anatomical and functional outcomes and complication rates were assessed. **Results:** The median follow-up was 66 months (range 60-108). Overall anatomical success rates (no recurrence of any prolapse ≥ stage II according to the pelvic organ prolapse-quantification system) were 86.0%. Urinary urgency and voiding dysfunction were significantly improved after surgery, however, recurrent stress urinary incontinence developed in 44.7% (21/47) of cases and half of them developed within 1-3 months post-op. Bowel function (constipation and fecal incontinence) and sexual function (sexual activity and dyspareunia) did not significantly change after surgery. Major complication requiring reoperation or intensive care developed in 12 (21.0%) cases. **Conclusion:** ASC provides durable pelvic support, however, it may be ineffective for alleviating pelvic floor dysfunction except for urinary urgency and voiding dysfunction, and it contains major complication risk that cannot be overlooked.

Key Words: Abdominal sacrocolpopexy, prolapse, treatment outcome

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INTRODUCTION

The true incidence of apical prolapse is not clear because most of previous epidemiologic studies were performed before 1996, in which the standardized system for evaluating pelvic organ prolapse (pelvic organ prolapse-quantification, POP-Q) was introduced. A recent study documented that in older women with an intact uterus, 14.2% had uterine prolapse.[1] Even though the incidence of posthysterectomy vault prolapse is also not clear, it has been reported to be 11.6% when hysterectomy was performed for genital prolapse and 1.8% when performed for other benign diseases.[2]

Many surgical approaches have been introduced to correct apical prolapse, however, abdominal sacrocolpopexy (ASC), proposed by Lane in 1962, has most widely been studied and has been shown to be reliable and durable.[3] Nonetheless, most previous studies reported short- or intermediate-term follow-up data, inadequately evaluated pelvic organ prolapse and have not addressed in detail the outcomes on pelvic floor dysfunction and major complications, for which reoperation or intensive care may be required. Moreover, many studies have reported the post-surgical results through inappropriate surgical techniques (i.e., simple attachment of mesh to vaginal apex instead of to the anterior and posterior vagina).

The aim of this study was to evaluate the long-term treatment outcome and

major complication rates of ASC.

MATERIALS AND METHODS

A total of 65 women underwent ASC for symptomatic uterine or vault prolapse at the Department of Obstetrics and Gynecology, Division of Female Pelvic Medicine and Reconstructive Surgery, Yonsei University Health System, Seoul, Korea between March 1999 and March 2003. Of them, 57 women who attended follow-up visits for at least 5 years were included in this retrospective study [8 women were excluded due to follow-up loss (n = 4) and short-term follow-up visits (n = 4)]. The study was approved by our Institutional Review Board.

All patients were preoperatively assessed through a standard history taking, pelvic examination and urodynamic study. Standard history taking consisted of age, parity, body mass index, menopause and hormone replacement therapy status, previous hysterectomy and pelvic reconstructive surgery, and urinary (urinary urgency, stress urinary incontinence, voiding dysfunction), bowel (constipation, fecal incontinence) and sexual (sexual activity, dyspareunia) symptoms. Urinary urgency and stress urinary incontinence were defined according to the recommendations of the International Continence Society.[4] Voiding dysfunction was defined as weak urine stream or urinary retention. Constipation was evaluated according to Rome II criteria.[5] Fecal incontinence was defined as the involuntary loss of solid or liquid stool per rectum. The woman who had sexual intercourse more than once a month was considered "sexually active." Pelvic examinations were performed in a 45° upright sitting position during a Valsalva's maneuver with maximal effort by the same examiner (S.W. Bai). Pelvic organ prolapse was quantified according to the POP-Q system.[6] Urodynamic studies (Dantec-5000, Copenhagen, Denmark) included uroflowmetry, multichannel cystometry, measurements of Valsalva leak point pressure, and urethral pressure profilometry. Measurements of Valsalva leak point pressure were performed with bladder volumes of 200 mL with manual reduction of prolapse.

All procedures were performed by one senior surgeon (S.W. Bai). Teflon (polytetrafluoroethylene, CR Bard, Covington, GA, USA) and Marlex mesh (polypropylene, CR Bard, Covington, GA, USA) were employed during this study period. The mesh was fashioned from two sheets, both 10 cm in length and tapering from a width of 5 cm at the vaginal end to 3 cm at the sacral end. The surgical techniques were as follows:

Surgical techniques

The patients were placed in a dorsal lithotomy position in Allen-type stirrups. Laparotomy was performed through a Pfannenstiel incision. For patients with urodynamic stress incontinence, a modified Burch colposuspension was performed with non-absorbable sutures (2-0 prolene, monofilament polypropylene) prior to entering the peritoneal cavity as previously described.[7] After entering peritoneal cavity, hysterectomy was performed. If the uterus had already been removed, after identifying the vaginal vault, its overlying peritoneum was dissected away, exposing the superior aspects of the pubocervical and rectovaginal fascia to provide a sufficiently broad area of at least 3×5 cm for attaching the mesh. Then, the peritoneum over the sacral promontory was incised vertically and loose areolar tissues were gently dissected to expose the anterior longitudinal ligament overlying the sacrum, taking care to avoid the injury of presacral vessels. The peritoneal incision was extended to the posterior cul-de-sac with caution to avoid damage to the rectum or the ureter. Three non-absorbable sutures (5-0 black braided silk sutures, Mersilk) were placed just below the level of the sacral promontory and the sutures were tagged with curved hemostat clamps. Then, elevating the vaginal vault cephalad using sponge sticks placed into the vagina, three delayed absorbable sutures (2-0 polysorb, coated braided lactomer) were placed on the anterior and posterior vaginal wall, one delayed absorbable suture (2-0 polysorb, coated braided lactomer) on each side of the vaginal vault, respectively. The sutures were brought through the two pieces of mesh, tied down, and cut. The appropriate length of the mesh was determined as one that avoids any tension on the mesh and vagina. The excess mesh was cut and removed, and the promontory sutures were then brought through the remaining mesh and tied down. After betadine irrigation, retroperitonealization of the mesh was performed with interrupted 2-0 cat-gut chromic sutures. Then, the abdomen was closed in the usual manner. Posterior colporrhaphy was done in all but one woman to treat remnant posterior defects.

Patients were followed up at 1, 3, 6, and 12 months after surgery, and annually thereafter. At each visit, urinary, bowel, and sexual symptoms, and other problems were assessed by the same physician (S.W. Bai). The changes of POP-Q stage were also examined.

The Mann-Whitney U test, Fisher's exact test and chi-square test were used for statistical analysis using the SPSS software 14.0 (SPSS Inc, Chicago, IL, USA). A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1 shows preoperative clinical and demographic characteristics of the study population. The median follow-

up was 66 months (range 60-108).

Anatomical treatment outcomes

Anatomical success rates were 100% when defined as lack of apical prolapse ≥ stage II postoperatively, and 86.0% when defined as no recurrence of any prolapse ≥ stage II (Table 2). All recurrences were observed in cases having undergone concomitant modified Burch colposuspension. However, when compared to cases not having undergone concomitant Burch colposuspension, there was no significant difference in recurrence rates of anterior prolapse (3/47 vs. 0/10, p = 1.000) and posterior prolapse (7/47 vs. 0/10, p = 0.333). The median recurrence time was 18 months (range 3-60 months). Five women experienced the recurrence within 2 years [2 (3 months), 1 (6 months), 1 (12 months), and 1 (24 months)], however, 3 had relapse of prolapse after 2 years [1 (48 months), 1 (36 months), and 1 (60 months)]. Two women with symptomatic recurrent prolapse were treated using pessary.

Table 1. Preoperative Characteristics of the Study Population

	Study group (n = 57)
Age (yrs, mean ± SD)	62.2 ± 10.0
Parity (median, range)	3 (1 - 10)
Body mass index (kg/m^2, mean ± SD)	24.1 ± 2.9
Menopause (n, %)	52 (91.2)
Hormone replacement therapy (n, %)	8 (15.4)
Prior hysterectomy (n, %)	19 (33.3)
Prior pelvic reconstruction (n, %)	6 (10.5)
POP-Q stage (n, %)	
III	24 (42.1)
IV	33 (57.9)

POP-Q, pelvic organ prolapse-quantification.

Functional outcomes

Following surgery, overall urinary function was significantly improved, however, 44.7% (21/47) of women experienced recurrent stress urinary incontinence, which was defined as the presence of stress-incontinence symptom and positive cough stress test after surgery (Table 3). The median recurrence time was 3 months (range 1-84 months). Of them, 2 underwent reoperation [1 (sling operation, cured), and 1 (tension-free vaginal tape, not cured)]. The incidences of *de novo* urinary urgency, *de novo* stress urinary incontinence, and *de novo* voiding dysfunction were 5/35 (14.3%), 1/10 (10.0%), and 1/46 (2.2%) respectively. Of 13 women who had constipation preoperatively, 3 (23.1%) had persistent symptoms after surgery. Three (6.8%) women complained of newly developed constipation following surgery. One woman who had fecal incontinence preoperatively, still had symptoms after surgery and another

Table 2. Pre- and Postoperative (at Last Follow-Up Visit) POP-Q Stages

Compartment	Stage	Preoperative (n, %)	Postoperative (n, %)
Apical	0	0	52 (91.2)
	I	0	5 (8.8)
	II	11 (19.3)	0
	III	17 (29.8)	0
	IV	29 (50.9)	0
Anterior	0	1 (1.8)	48 (84.2)
	I	1 (1.8)	6 (10.5)
	II	2 (3.5)	2 (3.5)
	III	23 (40.4)	1 (1.8)
	IV	30 (52.6)	0
Posterior	0	0	42 (80.7)
	I	0	8 (12.3)
	II	13 (22.8)	5 (7.0)
	III	19 (33.3)	2 (3.5)
	IV	25 (43.9)	0
Overall	0	0	36 (63.2)
	I	0	13 (22.8)
	II	0	6 (10.5)
	III	24 (42.1)	2 (3.5)
	IV	33 (57.9)	0

POP-Q, pelvic organ prolapse-quantification.

Table 3. Pre- and Postoperative (at Last Follow-Up Visit) Pelvic Floor Dysfunction

	Preoperative	Postoperative
Urinary urgency (n, %)	22 (38.6)	8 (14.0)*
Stress urinary incontinence (n, %)	47 (82.5)	22 (36.8)*
Voiding dysfunction (n, %)	11 (19.3)	2 (3.5)*
Constipation (n, %)	13 (22.8)	6 (10.5)
Fecal incontinence (n, %)	1 (1.8)	2 (3.5)
Sexual inactivity (n, %)	37 (64.9)	38 (66.7)
Dyspareunia (n, %)	2 / 20 (10.0)	2 / 20 (3.5)
Aware of prolapse (n, %)	57 (100)	2 (3.5)*

*p value < 0.05 (compared with preoperative status).

Table 4. Periop- and Postoperative Complications

Complication	n (%)
Intraoperative blood loss requiring transfusion	3 (5.3)
Intraoperative bladder, ureter and bowel injury	0
Deep vein thrombosis	1 (1.8)
Wound infection	1 (1.8)
Incisional hernia	3 (5.3)
Ureteral obstruction	
Teflon mesh (n = 26)	0
Marlex mesh (n = 31)	2 (6.5)
Small bowel obstruction	
Teflon mesh (n = 26)	0
Marlex mesh (n = 31)	1 (1.8)
Vault healing problem	
Teflon mesh (n = 26)	4 (15.4)
Marlex mesh (n = 31)	0
Reoperation for the complication	8 (14.0)*

*Reason for reoperation; 1 (deep vein thrombosis), 2 (mesh infection), 2 (right ureteral obstruction), 3 (incisional hernia).

woman complained of *de novo* fecal incontinence. Thirty-seven women who had been sexually inactive preoperatively did not resume sexual activity after surgery. Of 20 sexually active subjects before surgery, 1 (5.0%) did not have sexual intercourse after surgery because of dyspareunia due to mesh erosion.

Complications

The incidences of peri- and postoperative complications are presented in Table 4. Major complication requiring reoperation or intensive care developed in 12 (21.0%) cases. Two women were hospitalized for a long period due to wound infection or small bowel obstruction. And 8 women underwent reoperation for the complication. One experienced deep vein thrombosis at the postoperative third day and required thrombectomy because of no response to medical treatment. Three experienced incisional hernia and underwent reoperation (at 4 months, 4 years, and 6 years after surgery). Right ureteral obstruction occurred 3 years post op in 2 cases and they underwent reoperation (1 underwent stent insertion and 1 received right nephrectomy). Vaginal vault healing problems were noted only in cases using Teflon mesh [4/26 vs. 0/31 (Teflon mesh), $p = 0.038$]. Of the 38 women who underwent a hysterectomy at the time of ASC, 4 (20.0%) had erosion, but, no mesh erosion occurred ($p = 0.290$) in 19 women who did not receive a hysterectomy concomitantly. All events happened between 1 to 3 years after surgery. Two cases were cured by the long-term treatment with local estrogen and antibiotics, and in the rest 2 cases, conservative treatment failed because of infection and reoperation was performed for mesh removal.

DISCUSSION

In spite of extensive studies on the treatment outcomes of ASC, there have been few reports on its long-term efficacy and safety. Moreover, in previous studies those presenting a long-term outcome, adequate information cannot be acquired because of inadequate evaluation of pelvic organ prolapse, poor description of the pelvic floor dysfunction, and the use of inappropriate surgical techniques (Table 5).[7-11]

In the present study, we confirmed the long-term efficacy of ASC. The anatomical success rates were 100% for apical prolapse and 86.0% for any prolapse. Failures after ASC typically occur in other compartments, which have been reported as having values up to 29% and 57% in the anterior and posterior compartments, respectively.[12,13] Besides the difference in pelvic organ prolapse evaluation system employed and definition of recurrence, relatively low recurrence rates in the present study can be explained by the difference in surgical techniques. There have been several modifications in the surgical techniques used since the introduction of particular surgical techniques by Lane. One major difference is the attachment of the mesh to the

Table 5. Previously Reported Literatures Reporting on the Long-Term Outcomes after Sacrocolopexy

Author	No. Pts (No. lost)	Follow-up (yrs)	Mesh	Success rates (%)		Functional outcomes (%)	Major complications (%)
				Apical	Overall		
Podratz, et al.[8]*	50 (4)	5.8 (0.7 - 13.4)	Teflon (30), Others (12)†	97.8‡	87.0‡	Recurrent SUI (28.6), *de novo* SUI (8.0), *de novo* DP (4.3)	Ureteral injury / transfusion (0), bladder injury (5.0), hematoma / infection (6.0), DVT (2.0), mesh problem (4.3), incisional hernia (6.5)
Nieminen, et al.[9]*	26 (6)	7.3 (5.2 - 14.9)	Mersilene (5)§	85.0‡	40.0‡	*de novo* SUI (11.5), bowel, dysfunction (19.2), sexually active (35), *de novo* DP (11.1)	Bladder, bowel, ureteral injury (0), wound in fection (11.5), hematoma (3.8), incisional hernia (15.3)
Lefranc, et al.[7]	85 (0)	10.5 (2 - 20)	Mersilene	97.6‡	90.6‡	Recurrent SUI (40.4), *de novo* SUI (0), urinary urgency (14.0)	Intraoperative complication (0), transfusion for postoperative bleeding (2.4), phlebitis (3.5), bowel obstruction and mesh erosion/infection (0)
Reddy, et al.[10]	11 (0)	5	Prolene	100‡	81.8‡	*de novo* SUI (50.0)	Perop- or immediate postoperative complication (0), mesh erosion with sinus formation (9.1)
Hilger, et al.[11]*	69 (31)	13.7 (10 - 17)	Marlex	-	73.7‖	Recurrent SUI (84.0), *de novo* SUI (53.8), sexually active (50.0), DP (35.7)	Transfusion (6), mesh erosion (2.6), bowel obstruction (0)

SUI, stress urinary incontinence; DP, dyspareunia; DVT, deep vein thrombosis.
Only 13 (41.9%) patients were examed by pelvic organ prolapse-quantification system.
*Mesh was attached to only vaginal apex or vaginal apex and anterior vagina instead of the anterior and posterior vagina.
† Others included Marlex, Mersilene, or Gore-Tex. The rest 8 used fascia lata.
‡ Evaluation of prolapse was not clearly described or different between before and after surgery.
§ Mesh was used in 5 cases. The rest used rectus fascia (14) or allograft (dura mater, 3) or directly attached the vaginal apex to presacral fascia (4).
‖ Failure was defined as no operation for pelvic organ prolapse or a positive answer to question 5 on the PFDI questionnaire.

anterior and posterior vaginal walls, not simply to the vaginal apex. This modification can lead to good support of the anterior and posterior compartments as well as of the apical compartment, reinforcing and treating the vaginal fascial defects at DeLancey's levels 1 and 2.[7] Modified Burch colposuspension concomitantly performed with ASC can also affect the recurrence rates of anterior and posterior prolapse, however, we were not able to find any significant influence in this study. In the study investigating the recurrence rates using POP-Q system, Culligan, et al.[14] noted that nearly all recurrences occurred within 2 years postop and concluded that it is reasonable to construct randomized controlled trials involving ASC that only a 1- or 2 year follow-up. However, only 30% of women were followed up at least 4 years after surgery, and 22.4% of them were evaluated according to POP-Q in his study. In our study, the median recurrence time was 18 months. Nearly half of the recurrence occurred after 2 years. These findings indicate that short- or intermediate-term follow-up is not enough in studies involving ASC.

Also, the long-term outcomes of pelvic floor dysfunction (except in the case of stress urinary incontinence) after ASC have been poorly described in previous studies. Most studies have shown that Burch colposuspension combined with sacrocolpopexy is less effective than Burch colposuspension alone.[8-12,15,16] Similarly, nearly half of the women in our study experienced recurrent stress urinary incontinence and half of them developed within a postoperative period of 1-3 months, corresponding with the resumption of normal activity. These cases might have been due to the effect of ASC, since there was no case with low maximal urethral pressure (≤ 20 cmH_2O) on preoperative urodynamic study. ASC may flatten the anterior vaginal wall and urethrovesical angle, and the opposite forces resulting from ASC and Burch colposuspension might have been responsible for suboptimal Burch colposusension results.[8] Fur-

ther studies will be needed to evaluate whether another procedure such as a sling improves continence status further.

In the present study, urinary urgency and voiding dysfunction were significantly improved, possibly as a result of prolapse correction, however, bowel functions were not improved after surgery. This finding is consistent with the results of other studies.[3] Lack of bowel function improvement may be explained by the fact that bowel function can be influenced by several pathologic conditions besides rectocele. In one study, women with preoperative pathologic transit conditions and paradoxic sphincter reaction had constipation after rectocele repair.[17] Sexual activity also did not change after surgery. The impact of prolapse itself on sexual activity may be little. The main causes of preoperative sexual inactivity in this study population were an absent partner (40.5%) and no desire for sexual intercourse (48.7%). The rest of causes was partner's illness (5.4%) and patient's underlying illness (5.4%). All patients with preoperative sexual inactivity did not resume sexual activity postop.

Complications of ASC have also been poorly described in previous studies except for intraoperative complications (i.e., massive bleeding, visceral organ injury) and mesh erosion. We found significantly high rates of major complication requiring readmission for intensive care or reoperation, which may be partly due to the use of inappropriate mesh; that is, Teflon mesh. Teflon mesh is type III mesh, which has microporous component, and prone to infection and subsequent wound healing problem.[18] A recent study showed a significant high risk of mesh erosion in women who had polytetrafluoroethylene (Teflon, or Goretex) mesh compared to those with non-polytetrafluoroethylene mesh.[19] Concomitant hysterectomy might also have contributed to high mesh erosion rate.[19] Even though no significant difference was found in this study because of relatively small number of the study population, mesh erosion occurred only in women who had undergone concomitant hysterectomy.

The major weakness of this study was retrospective in nature and the small sample size. However, the percentage of follow-up loss was low (12.0%) compared with other studies. In addition, we used the standardized POP-Q system for the evaluation of prolapse and thoroughly investigated pelvic floor dysfunction and its complications. The second drawback was the lack of use of validated questionnaires on pelvic floor dysfunction, which were not available for us in this study period. Instead using validated questionnaires, we tried to assess pelvic floor dysfunction symptoms according to specific definitions or criteria.

ASC provides durable pelvic support, however, it may be ineffective for alleviating pelvic floor dysfunction except for urinary urgency and voiding dysfunction, and it contains major complication risk that cannot be overlooked.

Large population-based long-term follow-up studies using disease-specific validated questionnaires on pelvic floor dysfunction are needed in the future to draw a more definite conclusion.

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